



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/801,783	03/16/2004	Victor I. Chormenky	1004.012	3117

7590 11/17/2006

Law Offices
P.O. Box 386353
Bloomington, MN 55438

EXAMINER

TOY, ALEX B

ART UNIT	PAPER NUMBER
----------	--------------

3739

DATE MAILED: 11/17/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/801,783	CHORNENKY ET AL.	
	Examiner	Art Unit	
	Alex B. Toy	3739	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 September 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-14 and 20-23 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-8 and 20-23 is/are rejected.
- 7) ☒ Claim(s) 9-14 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 07 September 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Amendment

This Office Action is in response to applicant's amendment filed on September 7, 2006. The objections to the drawings and claim 8 are withdrawn in view of applicant's amendments.

Specification

The disclosure is objected to because of the following informalities: In applicant's amendment to paragraph 39 of the specification, "iin" should be changed to – in –, "the Figure" should be changed to – Figure 1 –, and in "substantially in the same plane as that defined by the electrode 60" should be changed to – electrode 58 –.

Appropriate correction is required.

Claim Objections

Applicant is advised that should claim 2 be found allowable, claim 21 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof.

Applicant is advised that should claim 3 be found allowable, claim 22 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof.

Applicant is advised that should claim 4 be found allowable, claim 23 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof.

When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper

Art Unit: 3739

after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

Claims 9-14 are objected to because of the following informalities: Regarding claim 9, line 9, "follicle.," should be changed to – follicle, –.

Appropriate correction is required.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-4, 6-8, and 20-23 are rejected under 35 U.S.C. 102(e) as being anticipated by Dev (U.S. PGPub 2002/0099323 A1).

Regarding claim 1, Dev discloses an apparatus for providing hair removal therapy to a patient, said apparatus comprising:

a high voltage pulse generator providing electrical pulses of sufficient duration and electric field strength to exceed the upper electroporation limit of hair follicles (pg. 8, ¶ 92); and

an applicator electrically connected to said pulse generator, said applicator including a central electrode 120, said central electrode being provided for non-invasive

engagement of a hair follicle of the patient and for being provided only for electroporation therapy, and an outer electrode 210 surrounding the central electrode (pg. 8, ¶ 91 and Fig. 2),

wherein said generator supplies pulses to said electrodes to create an electroporating field (pg. 8, ¶ 92) causing hair follicle death when said central electrode is placed into contact with a hair follicle.

The preceding paragraphs recite intended use. Since the structure of Dev anticipates the structure as claimed, the device of Dev is inherently capable of the claimed use.

Regarding claims 2 and 21, Dev discloses the apparatus of claim 1 wherein said central electrode 120 is a rod-like electrode (Fig. 2).

Regarding claims 3 and 22, Dev discloses the apparatus of claims 1 and 2 wherein said outer electrode 210 has an annular configuration (Fig. 2).

Regarding claims 4 and 23, Dev discloses the apparatus of claims 1-3 wherein said generator produces pulses having a duration exceeding 1 microsecond (pg. 10, ¶ 110).

Regarding claim 6, Dev discloses the apparatus of claim 1 wherein said central electrode 120 is a needle electrode (pg. 8, ¶ 91 and Fig. 2).

Regarding claim 7, Dev discloses the apparatus of claims 1 and 6 wherein said outer electrode has an annular configuration (Fig. 2).

Regarding claim 8, Dev discloses the apparatus of claims 1, 6, and 7 wherein said generator produces pulses having a duration exceeding 1 microsecond (pg. 10, ¶ 110).

Regarding claim 20, Dev discloses the apparatus of claim 1 wherein said outer electrode 430 defines a plane and said central electrode 420 includes a tip, said central electrode tip lying substantially in said defined plane when said apparatus is used for hair removal (Figs. 4A-B).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over Dev ('323) in view of Bernard (U.S. Pat. No. 6,912,417 B1).

Regarding claim 5, Dev discloses the apparatus of claims 1-3. The claim differs from Dev in calling for said generator to produce pulses having a duration in the range of 0.1 nanosecond to 1 microsecond. Bernard, however, teaches an electroporating needle for delivering therapeutic agents into tissue, wherein a generator produces pulses having a duration in the range of 0.1 nanosecond to 1 microsecond (col. 12, ln. 21-22). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have used a pulse duration of 1 microsecond in the device of Dev in view of the teaching of Bernard as an obvious alternate pulse duration for delivering therapeutic agents into tissue that is known in the art.

In addition, applicant has not disclosed any criticality or unexpected result associated with this range that defines over the longer pulse durations disclosed by Dev. On page 12 of the specification, applicant recites that "pulse duration can be ... in the range of about .1 nanosecond to one microsecond or they can be longer than microsecond."

Allowable Subject Matter

Claims 9-14 would be allowable if claim 9 is amended to correct the minor informality.

Response to Arguments

Applicant's arguments have been fully considered but they are not persuasive.

Regarding claim 1:

In response to applicant's argument that that Dev does not teach the generator of amended 1, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim.

The generator of Dev is inherently capable of providing electrical pulses as claimed. Regardless of whether Dev discloses causing hair follicle death, the generator of Dev is still inherently capable of operating at a voltage and pulse length to perform the claimed intended use.

In response to applicant's argument that said central electrode is provided for non-invasive engagement of a hair follicle of the patient and is provided only for electroporation therapy, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim.

The device of Dev is inherently capable of being used for non-invasive engagement of a hair follicle and providing only electroporation therapy.

Regarding claim 20:

Applicant argues that Figs. 4A-B of Dev do not show that said outer electrode 430 defines a plane and said central electrode 420 includes a tip, said central electrode

tip lying substantially in said defined plane when said apparatus is used for hair removal.

The examiner maintains that in Figs. 4A-B of Dev (U.S. PGPub 2002/0099323 A1) as previously cited by the examiner, the tip of central electrode 420 is clearly substantially in the plane defined by outer electrode 430.

Furthermore, the device of Dev as shown in either Fig. 2 or Figs. 4A-B is inherently capable of being positioned as claimed when performing the claimed intended use of hair removal.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.


Art Unit: 3739

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alex B. Toy whose telephone number is (571) 272-1953. The examiner can normally be reached on Monday through Friday, 8:00 AM to 4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda C.M. Dvorak can be reached on (571) 272-4764. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

AT *AT*
11/9/06


LINDA C. M. DVORAK
SUPERVISORY PATENT EXAMINER
GROUP 3700